

### **REMARKS**

Claims 21, 23, 26-28, 32, 35, and 37 are currently pending. Claims 1-20, 22, and 30 were previously cancelled and claims 24, 25, 29, 31, 33, 34, and 36 are cancelled by this amendment. Claims 21, 23, 26-28, 32, and 35 are currently amended and new claim 37 is added. Support for the amendments, which require that the composition used in the claimed methods comprise BMP-9, may be found in previously pending claims 25, 31, and 34, and throughout the specification, e.g., at page 5, lines 18-20 and page 6, lines 5-6. No new matter is added by this amendment.

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 21, 23, 26-28, 32, 35, and 37 in condition for allowance. Applicants submit that the proposed claim amendments do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicants respectfully point out that the final action by the Examiner presented some new arguments as to the application of the art against Applicant's invention. It is respectfully submitted that the entering of the Amendment would allow the Applicant to reply to the final rejections and place the application in condition for allowance.

Finally, Applicant submits that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

### **REJECTION UNDER 35 U.S.C. § 103**

The Examiner has rejected all the previously pending claims as allegedly obvious over U.S. Patent No. 6,761,887 (“the ’887 patent”) in view of Minas et al., *Orthopedics* 20(6):525-38 (1997) (“Minas”). The Examiner contends that the ’887 patent teaches methods for inducing chondrogenesis using an alginate layer system formed by seeding mesenchymal stem cells (“MSCs”) in alginate. The Examiner notes that MSCs express CD105. The Examiner further contends that the ’887 patent teaches that BMP-2 may be used as a chondrogenic agent. Minas et al. simply teaches autologous chondrocyte implantation. The Examiner argues that it would be obvious to combine the teachings of the ’887 patent with the teachings of Minas to use autologous CD105+ cells with BMP-2 as a factor that would induce chondrogenesis because BMP-2 is known to be involved in chondrogenesis and the use of autologous cells is desirable because it avoids the side effects of non-autologous allografts.

The claimed invention is directed to a method for inducing chondrogenesis by administering non-culture expanded CD105+ cells in combination with BMP-9. The cited prior art, either alone or in combination, do not teach or suggest the use of BMP-9 in such a method. The addition of BMP-9 allows the methods to be practiced without a culture expansion step to increase the number of CD105+ cells. The use of non-culture expanded cells relies on the ability of BMP-9 to stimulate the chondrogenic potential of the non-culture expanded cells, and this ability was demonstrated for the first time in Applicants’ specification.

The Examiner contends that the cited art suggests that BMP-2 may be able to induce the chondrogenic potential of stem cells. However, the art does not provide a reasonable expectation of success in using non-culture expanded cells along with

BMP-9, or, for that matter, BMP-2, to induce chondrogenesis. The use of non-culture expanded cells is more difficult than the Examiner admits because one of skill in the art would not know if the cells will multiply and differentiate in the absence of culture expansion. The recitation of non-culture expanded cells as an alternative embodiment in the methods of the '887 patent does not actually demonstrate that the use of non-culture expanded cells would work to induce chondrogenesis. Thus, the '887 patent fails to provide the skilled artisan with a reasonable expectation of success in practicing Applicants' claimed methods.

Furthermore, a suggestion to use BMP-2 is not a teaching or suggestion to use BMP-9, which is only 53% homologous to BMP-2. Accordingly, cited art allegedly suggesting the use of BMP-2 provides no motivation to replace BMP-2 with BMP-9 or any reasonable expectation of success in doing so. Applicants respectfully request that the Examiner withdraw the rejection of the claims under 35 U.S.C. § 103 and allowance of the claims.

In view of the foregoing remarks, Applicant submits that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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Dated: April 6, 2007

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